K131097

Legacy3 6mmL Implants

510(K) Submission

510(K) Summary (21CFR 807.92(c))

1. **Submitter's Information:**

Company Name:	Implant Direct Sybron Manufacturing LLC
Address:	27030 Malibu Hills Rd., Calabasas Hills, CA USA 91301
Telephone:	818-444-3300
Fax:	818-444-3406
Registration No.:	3001617766
Contact:	Ines Aravena
Date Prepared:	May 15, 2013

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2. **Device Name and Classification:**
Device Trade Name: Legacy3 6mm Length Implants
Classification Names: Implant, Endosseous, Root-Form
Common Names: Endosseous Dental Implant
Regulation Number: 872.3640
Product Codes: DZE
Regulatory Class: II

3. **Predicate Device(s):**

Spectra Dental Implant System (K061319)
Implant Direct Legacy Dental Implants with HA Coating (K073033)
Implant Direct Spectra-System Implants 2008 (K090234)
Implant Direct SwissPlant Implants (K081396)
Bicon Implants with a 2.5mm Internal Connection (K092035)
The Bicon 5.0 X 5.0mm and 6.0 X 5.0mm Dental Implant (K073368)
ITI Dental Implant System (K030007)

4. **Device Description:**

The Legacy3 6mm length implants consists of two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

The Legacy3 6mm length implants have a taper body to facilitate insertion in an undersized socket and gradual expansion of bone to increase initial stability. The body has double-lead buttress threads and quadruple-lead threads in the coronal

K131097

region. The body offers two surface options: Soluble Blasted Media (SBM) texture throughout the entire length or SBM at the coronal section plus HA-coated the rest of the body length. The internal connection consists of leading bevel, a hex and a 1-72UNF thread to engage the mating components.

The Legacy3, 6mm length implants are a line extension to the previously cleared Legacy implants (K090234) having identical prosthetic interface compatibility. The addition is not due to recall, customer complaint, corrective action, or labeling and it does not affect its intended use. The addition provides a shorter version of the predicate implant in order to allow for a restoration option in areas of the mouth where an 8mm implant will not work.

The shorter version required minor changes to the outer body design taper and threads depth to allow for adequate thread engagement when using existing surgical protocol and have a surface area that is equal or greater than the predicate devices. The shorter 6mm length implants are equivalent to the existing SwishPlant 6mm implants (K081396) with clinically proven safety and efficacy.

The Legacy3 6mmL implants offer six body diameters (3.7, 4.2, and 4.7, 5.2, 5.7 and 7.0 mm) in 6mm length with the platform diameter of 3.5, 4.5 and 5.7mm. The Legacy3 6mmL implants are available with two surface coatings: SBM Blast and HA Coating. The Legacy3 6mm implants are surgically and functionally compatible with the previously cleared prosthetic components (K060063, K081101, K090234 and K061319), and currently marketed laboratory components and surgical armamentaria.

5. **Intended Use:**

Legacy3 6mm Length implants consist of two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

6. **Device Comparison (Technological Characteristics):**

This submission is comprised of devices whose physical dimensions, material composition, indications for use and methods of manufacture were previously cleared and have the same principles of operation as the cited predicate devices. The following Tables summarize the predicate device comparison analyses with the devices within the Legacy3 6mmL Implants. The subject device and the predicate devices have the same intended, the same technological characteristics, implant/abutment interface, similar material and surface treatment.

K131097

Legacy3 6mmL Implants

510(K) Submission

The table below compares the Legacy3 6mm Length Implants with currently marketed products. The comparison analysis consisted of the products' technological characteristics and intended use to support the substantial equivalency to their corresponding predicate devices.

Device Comparison Table: Legacy3 6mmL Dental Implants

Characteristics	Proposed: Legacy3 6mm	Own Predicate Device: Legacy 8mm (K073033, K090234	Own Reference Device: SwissPlant 6mm (K081396)	Predicate Device: Bicon Implants (K073368 and K092035)	Predicate Device: Straumann (K030007)	Substantial Equivalence
Part Numbers	853706, 854206, 854706, 855206, 855706, 857008 863706, 864206, 864706, 865206, 865706, 867008	853208, 853708, 854208, 854708, 855208, 855708, 857008	904106, 904806, 904806W, 905706	260-340-255	043.051S	√
Intended Use	The Legacy Dental Implant is a dental implant fixture that is a part of a two-piece implant system. The Legacy implants are intended for use in the mandible and maxilla, in support of single or multiple-unit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and	The Legacy Dental Implant is a dental implant fixture that is a part of a two-piece implant system. The Legacy implants are intended for use in the mandible and maxilla, in support of single or multiple-unit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and	The SwissPlant Dental Implant system consists of two-piece implants for one or two-stage surgical procedures that are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including: cement retained, screw retained or overdenture restorations and in terminal or immediate abutment support	Intended for surgical implantation in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary attachment for fixed or removable bridgework, or as a freestanding single tooth replacement	Intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In	√

K131097

	function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements.	function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements.	for fixed bridgework. The SwissPlant dental implants are intended for immediate placement and function on single tooth and/or multiple tooth applications recognizing initial implant stability and appropriate occlusal loading, to restore normal masticatory function.		case of edentulous patients 4 or more implants must be used	
Indication	Immediate Load	Immediate Load	Immediate Load	Unknown	Unknown	√
General Design	Threaded, root form implant	Threaded, root form implant	Threaded, root form implant	Groove type implant	Threaded, root form implant	√
Placement Method	Dual or single-stage surgery	Dual or single-stage surgery	Dual or single-stage surgery	Two or single stage surgery	Single stage surgery	√
Material	Titanium Alloy (Ti 6AL-4V ELI)	Titanium Alloy (Ti 6AL-4V ELI)	Titanium Alloy (Ti 6AL-4V ELI)	Commercially pure Titanium	Commercially pure Titanium	√
Implant Body	Threaded body without gingival collar	Threaded body without gingival collar	Threaded body with gingival collar	Grooved body without gingival collar	Threaded body with gingival collar	√
Body Diameter	3.7, 4.2, 4.7, 5.2, 5.7, 7.0mm	3.2, 3.7, 4.2, 4.7, 5.2, 5.7, 7.0mm	4.1, 4.8, 5.7mm	4.0, 5.0, 6.0mm	4.1, 4.8mm	√
Length	6mm	8mm	6mm	5mm	6mm	√
Platform Diameter	3.5, 4.5, 5.7mmD 853706, 863706, 854206 & 864206 - Ø3.5 platform 854706, 864706, 855206 & 865206 - Ø4.5 platform 855706, 865706, 857006 & 867006 - Ø5.7 platform	3.0,3.5, 4.5, 5.7mmD 853208 = Ø3.0 platform 853708 & 854208 - Ø3.5 platform 854708 & 855208 - Ø4.5 platform 855708 & 857008 - Ø5.7 platform	4.8, 6.5mmD 904106 & 904806 -Ø4.8mm platform 904806W & 905706 -Ø6.5mm platform	2.5 - 3.0mm	4.8 and 6.5mm	√
Implant Surface below bone	SBM HA coated /Single	SBM HA coated /Single	SBM HA coated /Single	Integra-Ti and Integra-CP	SLA and SLActive	√

K131097

level	Roughened	Roughened	Roughened or Dual Roughened			
Surface Roughness	SBM =1.5-2.3µm	SBM =1.5-2.3µm	SBM =1.5-2.3µm	Unknown	Unknown	√
Packaging	Inner sleeve to suspend the implant/fixture-mount assembly inside an outer vial sealed with a cap. Packaging also includes surgical cover screw, extender and temporary coping	Inner sleeve to suspend the implant/fixture-mount assembly inside an outer vial sealed with a cap. Packaging also includes surgical cover screw, extender and temporary coping	Inner sleeve to suspend the implant/fixture-mount assembly inside an outer vial sealed with a cap. Packaging also includes surgical cover screw, extender and temporary coping	Implants are packaged in a sealed plastic container with a Tyvek type sealed barrier and with a plastic carrier.	Double vial system. Inner sleeve to suspend the implant inside an outer vial sealed with a cap. Packaging also includes surgical cover screw	√
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Unknown	Unknown	√
510(k) Number		K073033 K090234	K081396	K073368 K092035	K030007	√

The Legacy3 6mmL implants were shown to be substantially equivalent to the predicate devices: Legacy 8mmL (K073033 and K090234), SwissPlant 6mmL Implants (K081396), Bicon Implants (K073368 and K092035), and Straumann Implants (K030007).

7. **Non-clinical Performance Testing:**

The devices in this submission have mechanical safety (strength) equivalent to the predicate devices. Laboratory testing was conducted for the worst-case devices following FDA "Class II Special Control Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" and ISO 14801 in static compression bending and fatigue, as well as implant driving torque and abutment/screw torque to failure tests. The components have shown to exhibit equivalent mechanical strength as the predicate devices and the implant/abutment combinations were able to withstand loads that were higher than the functional masticatory loads.

In addition, comparative surface area analysis was performed to demonstrate substantial equivalence by creating 3D models of the implants and obtaining the total external osseointegration surface area using three dimensional CAD measurement function. Furthermore, comparative pull-out testing was conducted

K131097

to demonstrate substantial equivalence by inserting the implants into simulated bone taking into account 3mm of potential bone loss.

Lastly, sterilization Validation was carried out in accordance with ISO 11137-2 and AAMI TIR-33 for gamma radiation.

8. Clinical Performance Testing

No clinical testing was performed. The clinical evaluation was used to support the decision of safety and effectiveness.

9. Conclusion:

The information submitted in this 510(k) for the Legacy3 6mmL Implants have shown that the devices are substantial equivalent to the device systems identified as predicates and it is considered that the new devices are as safe and effective for its indication for use, compatible and performs as well the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

August 22, 2013

Implant Direct Sybron Manufacturing LLC
Ms. Ines Aravena
Senior Director of Product Design and Regulatory Affairs
27030 Malibu Hills Road
CALABASAS HILLS CA 91301

Re: K131097
Trade/Device Name: Legacy3 6mm Length Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 23, 2013
Received: July 24, 2013

Dear Ms. Aravena:

We have reviewed your Section 510(k) premarket notification of intent to
referenced above and have determined the device is substantially equivale
for use stated in the enclosure) to legally marketed predicate devices mark
commerce prior to May 28, 1976, the enactment date of the Medical Devi
devices that have been reclassified in accordance with the provisions of th
and Cosmetic Act (Act) that do not require approval of a premarket appro
You may, therefore, market the device, subject to the general controls pro
general controls provisions of the Act include requirements for annual reg
devices, good manufacturing practice, labeling, and prohibitions against m

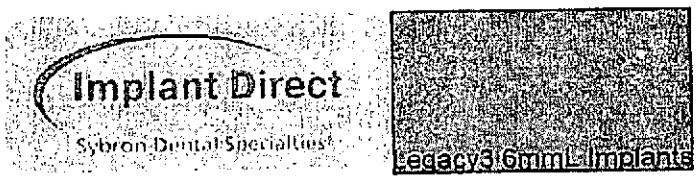
Please be advised that FDA's issuance of a substantial equivalence determ
that FDA has made a determination that your device complies with other r
or any Federal statutes and regulations administered by other Federal agen
comply with all the Act's requirements, including, but not limited to: regis
CFR Part 807); labeling (21 CFR Part 801); medical device reporting (rep
device-related adverse events) (21 CFR 803); good manufacturing practice
forth in the quality systems (QS) regulation (21 CFR Part 820); and if appl
product radiation control provisions (Sections 531-542 of the Act); 21 CF

If you desire specific advice for your device on our labeling regulation (21
contact the Division of Small Manufacturers, International and Consumer
free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.ht
the regulation entitled, "Misbranding by reference to premarket notificatio
807.97). For questions regarding the reporting of adverse events under the
CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm f
of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under t
Division of Small Manufacturers, International and Consumer Assistance
(800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.ht

Sincerely yours,

Mary S. Ru



Indications for Use

510(k) Number (if known): K131097

Device Name: Legacy3 6mm Length Implants

Indications for Use:

Legacy3 6mm Length consists of two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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Division Sign-Off)
ivision of Anesthesiology, General Hospital
fection Control, Dental Devices

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